THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today

- (1) was not written for publication in a law journal and
- (2) is not binding precedent of the Board.

Paper No. 28

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PRAKASH R. KESHAVIAH, JAMES P. EBBEN, PAUL EMERSON, and KAZUO KUMANO

Appeal No. 98-1316 Application 08/420,896¹

ON BRIEF

Before COHEN, MEISTER, and NASE, <u>Administrative Patent Judges</u>.

MEISTER, <u>Administrative Patent Judge</u>.

DECISION ON APPEAL

¹ Application for patent filed April 11, 1995. According to appellants, this application is a continuation of Application 08/223,806, filed April 6, 1994.

This is an appeal from the final rejection of claims 2-6, 8-13, 21 and 22, the only claims remaining in the application.²

We REVERSE and, pursuant to our authority under the provisions of 37 CFR § 1.196(b), enter a new rejection of the appealed claims under 35 U.S.C. § 112, first paragraph.

The appellants' invention pertains to a system and method for providing peritoneal dialysis to a patient. Independent claims 21 and 22 are further illustrative of the appealed subject matter and copies thereof may be found in the appendix to the appellants' brief.

The references relied on by the examiner are:

Gaudin	3,698,494	Oct.	17,	1972
Lee	4,649,759	Mar.	17,	1987
Romanelli et al. (Romanelli)	4,755,168	Jul.	5,	1988
Polaschegg	4,796,644	Jan.	10,	1989
Jacobsen et al.	5,141,493	Aug.	25,	1992
(Jacobsen)				

Claims 5, 11, 21 and 22 stand rejected under 35 U.S.C.

 $^{^{\}rm 2}$ Independent claims 21 and 22 have been amended subsequent to final rejection.

§ 102(b) as being anticipated by Jacobsen.

Claim 12 stands rejected under 35 U.S.C. § 103 as being unpatentable over Jacobsen.

Claims 2 and 8 stand rejected under 35 U.S.C. § 103 as being unpatentable over Jacobsen in view of Lee.

Claims 3 and 9 stand rejected under 35 U.S.C. § 103 as being unpatentable over Jacobsen in view of Romanelli.

Claims 4 and 10 stand rejected under 35 U.S.C. § 103 as being unpatentable over Jacobsen in view of Polaschegg.

Claims 6 and 13 stand rejected under 35 U.S.C. § 103 as being unpatentable over Jacobsen in view of Gaudin.

Each of the above-noted rejections is bottomed on the examiner's view that

Jacobsen discloses a catheter 12, a single circuit dialysate reservoir container (the entire fluid circuit 4 that is a source of dialysate fluid), and a single pump 72. Jacobsen discloses in column 4, lines 20-24 that a patient[']s peritoneal fill volume is typically from 1.5 to 3 liters. Jacobsen also discloses in column 4, line 55 that the dialysis system uses about 3 liters of dialysate to perform the dialysis instead of the normal 40 liters with other systems. Jacobsen discloses the volume of dialysate in the single circuit dialysate reservoir container as being about 1 and ½ times the patient[']s fill volume. [Answer, pages 3 and 4.]

Even if we were to agree with the examiner that the volume of dialysate in Jacobsen's system is about 1½ times the

patient's fill volume, we are of the opinion that the examiner, by contending that "the entire fluid circuit" (including a second pump 16, bubble trap 20, dialyzer 24, restriction 36 and three-liter bag 48) collectively comprise the reservoir container, is attempting to expand the meaning of "reservoir container" beyond all reason. While it is true that the claims in a patent application are to be given their broadest reasonable interpretation consistent with specification (In re Morris, 127 F.3d 1048, 1056, 44 USPQ2d 1023, 1028 (Fed. Cir. 1997) and In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989)) and limitations from a pending application's specification will not be read into the claims (*Sjolund v. Musland*, 847 F.2d 1573, 1581-82, 6 USPQ2d 2020, 2027 (Fed. Cir. 1988)), it is also well settled that terms in a claim should be construed in a manner consistent with the specification and construed as those skilled in the art would construe them (see In re Bond, 910 F.2d 831, 833, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990), Specialty Composites v. Cabot Corp., 845 F.2d 981, 986, 6 USPQ2d 1601, 1604 (Fed. Cir. 1988) and In re Sneed, 710 F.2d 1544, 1548, 218 USPQ 385, 388 (Fed. Cir. 1983)).

Here, the appellants have incorporated Fig. 1A of

Jacobsen into their drawings as Figure 2 and state on pages 4

and 5 of the specification that:

Figure 2 sets forth a figure from U.S. Patent No. 5,141,493 [i.e., Jacobsen]. Figure 2 illustrates the three loop system of the '493 patent wherein dialysate is reciprocated into and out of the patient using a reversible pump (first loop) into a second loop. In the second loop, the dialysate passes through a dialyzer being regenerated by non-sterile dialysate flowing in the third loop. The difference between the '493 system and the earlier systems is that both regeneration and reciprocation are continuous.

All of the above investigators have reported increased small molecule clearance and high ultrafiltration with either a continuous flow or reciprocating type systems. Naturally, an advantage of this type is desirable. However, these prior systems are quite complex in their operation, setup, and control.

More specifically, Jacobsen discloses a primary circuit 4 which includes a constant speed pump 16, bubble trap 20, dialyzer 24, restriction 36 and three-liter bag 48 (that allows the user to maintain some of the dialysate fluid flowing in the primary circuit 4; see column 5, lines 9-12). The dialysate fluid is alternately pumped by pump 72 from the circuit 4 into the patient and then back from the patient into circuit 4 where the dialysate fluid (which includes

containments in the form of waste products and excess water received from the patient) is pumped by constant speed pump 16 first to dialyzer 24 (which regenerates and purifies the dialysate fluid by removing the containments) and thereafter to the three-liter bag 48 (from where it can once again be pumped back into the patient). See, generally, column 3, line 67, through column 5, line 13.

According to the above-quoted portion of the specification, arrangements such as that of Jacobsen are "desirable" but "quite complex" in their operation, set-up and control. In an effort to provide a simplified system and procedure for achieving peritoneal dialysis, the appellants simply provide a reservoir container 28 for an amount of dialysate fluid that is at least about 1% times the volume of the peritoneal cavity of a patient and a single pump 24 is used for reversibly pumping the dialysate fluid back and forth from the patient to the reservoir container so that the dialysate fluid pumped from the patient (which contains more containments) is "diluted" by mixing it with the dialysate fluid in the reservoir container (which contains less containments). Although the concentration of containments in the dialysate fluid contained in the reservoir container

obviously progressively increases as the process goes on, a diffusive gradient is nevertheless maintained (see, generally, pages 9 and 20 of the specification).

Consistent with the appellants' specification, we can think of no circumstances under which the artisan would construe the entire circuit 4 of Jacobsen (which includes a constant speed pump 16, bubble trap 20, dialyzer 24, restriction 36 and three-liter bag 48) to collectively correspond to the claimed dialysate reservoir container. being the case, Jacobsen does not (1) have a single pump (claim 21), (2) possess the capability of having the dialysate fluid "returned directly to the reservoir container to dilute dialyzed waste products" (claim 21) or (3) teach the step of periodically pumping a smaller volume of dialysate fluid "directly back into the reservoir container for dilution with remaining dialysate fluid" (claim 22). We further find no teaching in Jacobsen of a fluid catheter having a "second end directly connected to a dialysate reservoir container" as expressly required by independent claims 21 and 22.

With respect to the rejections of (1) claims 3 and 9 where Romanelli is additionally relied on, (2) claims 2 and 8

where Lee is additionally relied on, (3) claims 4 and 10 where Polaschegg is additionally relied on and (4) claims 6 and 13 where Gaudin is additionally relied on, we have carefully studied these references but find nothing therein which would overcome the deficiencies of Jacobsen that we have noted above.

The examiner's rejections are all reversed.

Under the provisions of 37 CFR § 1.196(b) we make the following new rejection:

Claims 2-6, 8-13, 21 and 22 are rejected under 35 U.S.C. § 112, first paragraph, as being based upon an original disclosure which fails to provide descriptive support for the subject matter now being claimed. We initially observe that the description requirement found in the first paragraph of 35 U.S.C. § 112 is separate from the enablement requirement of that provision. See Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1560-64, 19 USPQ2d 1111, 1114-17 (Fed. Cir. 1991) and In re Barker, 559 F.2d 588, 591, 194 USPQ 470, 472 (CCPA 1977), cert. denied,

434 U.S. 1238 (1978). With respect to the description requirement, the court in *Vas-Cath, Inc. v. Mahurkar* at 935 F.2d 1563-64, 19 USPQ2d 1117 stated:

35 U.S.C. § 112, first paragraph, requires a

"written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed.

. . . drawings alone **may** be sufficient to provide the "written description of the invention" required by § 112, first paragraph.

With these authorities in mind, we have carefully reviewed the original disclosure and fail to find descriptive support for the recitation in independent claims 21 and 22 that the fluid catheter has "a second end directly connected to a dialysate reservoir container [i.e, element 28]."

Contrary to such an arrangement, the specification expressly states that the:

Fluid line 34 *terminates at a catheter* (not shown) that is in fluid communication with the peritoneal cavity of the patient 26. [Page 10, lines 25-27; emphasis added.]

See also Figures 3 and 4 of the drawing.

From the above, it is readily apparent that the second end of the catheter is directly connected to the fluid line 34, rather than to the reservoir container 28 as claimed.

In summary:

The examiner's rejections of 2-6, 8-13, 21 and 22 are all reversed.

A new rejection of claims 2-6, 8-13, 21 and 22 under 35 U.S.C. § 112, first paragraph, has been made.

This decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b)(amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)).

37 CFR § 1.196(b) provides that, "A new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that the appellants,

WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise

one of the following two options with respect to the new

ground of rejection to avoid termination of proceedings (§ 1.197(c)) as to the rejected claims:

- (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .
- (2) Request that the application be reheard under $\S 1.197(b)$ by the Board of Patent Appeals and Interferences upon the same record. . . .

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR $\S 1.136(a)$.

REVERSED 37 CFR § 1.196(b)

	Irwin Charles Cohen Administrative Patent	Judge))))	
PATENT	James M. Meister)	BOARD OF
	Administrative Patent	Judge)))	APPEALS AND INTERFERENCES
	Jeffrey V. Nase Administrative Patent	Judge)	

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